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World Intellectual Property Organization (WIPO) - Geneva, Switzerland  
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1312643

# THE UNITED STATES OF AMERICA

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**APPLICATION NUMBER: 60/544,009**

**FILING DATE: February 12, 2004**

**RELATED PCT APPLICATION NUMBER: PCT/US05/04532**



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**PROVISIONAL APPLICATION FOR PATENT COVER SHEET**

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

ER873481605US

U.S. PTO  
60/544009

02122004

**INVENTOR(S)**

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Darrell H.	Reneker	300 Hampshire Rd., Akron, OH 44313
Daniel J.	Smith	2988 Ridgeline Trail, Stow, OH 44224
Woraphon	Kataphinan	805 Yale St., #B, Akron, OH 44311

☐ Additional inventors are being named on the \_\_\_\_\_ separately numbered sheets attached hereto
**TITLE OF THE INVENTION (500 characters max)****IMPROVED STENT FOR USE IN CARDIAC, CRANIAL, AND OTHER ARTERIES**

Direct all correspondence to:

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Roetzel &amp; Andress

Address

222 South Main Street

Address

City

Akron

State

Ohio

ZIP

44308

Country

United States

Telephone

330-376-2700

Fax

330-376-4577

**ENCLOSED APPLICATION PARTS (check all that apply)**
☒ Specification Number of Pages

13

☐ CD(s), Number

☐ Drawing(s) Number of Sheets

☒ Other (specify)

postcard

☐ Application Data Sheet. See 37 CFR 1.76
**METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT**
☒ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees

☒ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:

50-0959

☐ Payment by credit card. Form PTO-2038 is attached.
FILING FEE  
AMOUNT (\$)

\$80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

SIGNATURE

*Daniel J. Schlue, Esq.*

Date

02/12/2004

TYPED or PRINTED NAME

Daniel J. Schlue

REGISTRATION NO.

(if appropriate)

Docket Number:

52,194

089498-0500

TELEPHONE 330-376-2700

**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of )

DARRELL RENEKER et al. )


Serial No. )

Filed )

For IMPROVED STENT FOR USE  
IN CARDIAC, CRANIAL, AND  
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**CERTIFICATE OF MAILING  
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I hereby certify that this correspondence was deposited  
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APPLICATION, Commissioner for Patents, P. O. Box  
1450, Alexandria, VA 22313-1450, on February 12,  
2004.

  
Faye Leppa Sec'y to Daniel J. Schlue  
Express Mail Label No. ER873481605US

**TRANSMITTAL SHEET**

Enclosed are the following documents:

Provisional Application Cover Sheet


Provisional Patent Application

Return Receipt Postcard

**AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT**

The Director is hereby authorized to charge payment of any fees associated with this  
communication or credit any overpayment to Deposit Account No. 50-0959 (089498-0500).

Respectfully submitted

  
Daniel J. Schlue, Reg. No. 52,194  
Roetzel & Andress  
222 South Main St.  
Akron, Ohio 44308  
(330) 376-2700

Attorney for Applicant

February 12, 2004

089498-0500 / 1145082\_1

## UA.500 Claims

1. A stent comprising:  
an external fibrous layer that is loosely wrapped around the stent.
2. The stent of claim 1, wherein the external fibrous layer comprises a nanofiber.
3. The stent of claim 1, wherein the external fibrous layer comprises polyethyleneoxide, polyethylene glycol, polyethylene oxazoline, polyester, polycaprolactone, polyacrylic acid, polyacrylic acid esters, polyhydroxyethylmethacrylate, polyvinyl pyrrolidone, polyphosphazines, polycyanoacrylate, polyvinyl amines, polyethylene imines, polyethylene amines, polyacrylamides, cellulose, cellulose derivatives, proteins, polyorthoesters, polyanhydrides, polyketals, polyacetals, polyureas, and polycarbonate, or a combination thereof.
4. The stent of claim 1, wherein the external layer comprises a thrombogenic material that initiates the formation of a thrombus.
5. The stent of claim 4, wherein the thrombus blocks the entrance to an aneurysm or an opening in a blood vessel wall.
6. A method for manufacturing a stent having an external fibrous layer that is loosely wrapped around the stent comprising the steps:  
coating a stent's external surface with a first layer;  
coating the outer surface of the first layer with a second fibrous layer; and  
removing the first layer thereby leaving the second fibrous layer loosely wrapped around the stent.
7. The method of claim 6, wherein the first layer is soluble and the second fibrous layer is insoluble in a liquid.

8. The method of claim 6, wherein the first layer can be degraded to a soluble or gaseous species by enzymes, small molecules, or other reactive substances.
9. The method of claim 6, wherein the first layer comprises polyethyleneoxide, polyethylene glycol, polyethylene oxazoline, polyester, polycaprolactone, polyacrylic acid, polyacrylic acid esters, polyhydroxyethylmethacrylate, polyvinyl pyrrolidone, polyphosphazines, polycyanoacrylate, polyvinyl amines, polyethylene imines, polyethylene amines, polyacrylamides, cellulose, cellulose derivatives, proteins, polyorthoesters, polyanhydrides, polyketals, polyacetals, polyureas, and polycarbonate, or a combination thereof.
10. The method of claim 6, wherein the second fibrous layer comprises a thrombogenic agent.
11. The method of claim 10, wherein the thrombogenic agent is fibrinogen, collagen, or a combination thereof.
12. The method of claim 6, wherein the first layer comprises a nanofiber.
13. The method of claim 6, wherein the second fibrous layer comprises a nanofiber.
14. The method of claim 6, wherein the step of coating the stent's external surface is accomplished via electrospinning.
15. The method of claim 6, wherein the step of coating the outer surface of the first layer with a second fibrous layer is accomplished via electrospinning.
16. A method for using a stent having an external fibrous layer that is loosely wrapped around the stent comprising the step of employing the stent in a living organism.
17. A balloon catheter comprising:

an external fibrous layer that is loosely wrapped around the balloon catheter.

18. The balloon catheter of claim 17, wherein the external fibrous layer comprises a nanofiber.
19. The balloon catheter of claim 17, wherein the external fibrous layer comprises polyethyleneoxide, polyethylene glycol, polyethylene oxazoline, polyester, polycaprolactone, polyacrylic acid, polyacrylic acid esters, polyhydroxyethylmethacrylate, polyvinyl pyrrolidone, polyphosphazines, polycyanoacrylate, polyvinyl amines, polyethylene imines, polyethylene amines, polyacrylamides, cellulose, cellulose derivatives, proteins, polyorthoesters, polyanhydrides, polyketals, polyacetals, polyureas, and polycarbonate, or a combination thereof.
20. The balloon catheter of claim 17, wherein the external layer comprises a thrombogenic material that initiates the formation of a thrombus.
21. The balloon catheter of claim 20, wherein the thrombus blocks the entrance to an aneurysm or an opening in a blood vessel wall.
22. A method for manufacturing a balloon catheter having an external fibrous layer that is loosely wrapped around the balloon catheter comprising the steps:
  - coating a balloon catheter's external surface with a first layer;
  - coating the outer surface of the first layer with a second fibrous layer; and
  - removing the first layer thereby leaving the second fibrous layer loosely wrapped around the balloon catheter.
23. The method of claim 22, wherein the first layer is soluble and the second fibrous layer is insoluble in a liquid.
24. The method of claim 22, wherein the first layer can be degraded to a soluble or gaseous species by enzymes, small molecules, or other reactive substances.

25. The method of claim 22, wherein the first layer comprises polyethyleneoxide, polyethylene glycol, polyethylene oxazoline, polyester, polycaprolactone, polyacrylic acid, polyacrylic acid esters, polyhydroxyethylmethacrylate, polyvinyl pyrrolidone, polyphosphazines, polycyanoacrylate, polyvinyl amines, polyethylene imines, polyethylene amines, polyacrylamides, cellulose, cellulose derivatives, proteins, polyorthoesters, polyanhydrides, polyketals, polyacetals, polyureas, and polycarbonate, or a combination thereof.
26. The method of claim 22, wherein the second fibrous layer comprises a thrombogenic agent.
27. The method of claim 26, wherein the thrombogenic agent is fibrinogen, collagen, or a combination thereof.
28. The method of claim 22, wherein the first layer comprises a nanofiber.
29. The method of claim 22, wherein the second fibrous layer comprises a nanofiber.
30. The method of claim 22, wherein the step of coating the balloon catheter's external surface is accomplished via electrospinning.
31. The method of claim 22, wherein the step of coating the outer surface of the first layer with a second fibrous layer is accomplished via electrospinning.
32. A method for using a balloon catheter having an external fibrous layer that is loosely wrapped around the balloon catheter comprising the step of employing the balloon catheter in a living organism.

The following references are part of this application:

WO 02/49535A2

WO 03/035134

EP 1329230

WO 03/082368

U.S. 2003/0088307

U.S. 2003/0135255

U.S. 2003/0190341

U.S. 2003/0211135A1

5,632,772

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(UARF07 6/02)

Disclosure No.: 4A-500  
(University to provide)

- Address 805 Yale St. # B Akron, OH 44311

- (b) Full name (including full middle name), home address, and citizenship of those who contributed to subsequent development and testing.

Name \_\_\_\_\_ Citizen of \_\_\_\_\_

Address \_\_\_\_\_

Name \_\_\_\_\_ Citizen of \_\_\_\_\_

Address \_\_\_\_\_

Name \_\_\_\_\_ Citizen of \_\_\_\_\_

Address \_\_\_\_\_

12. Conception of discovery or invention.

- (a) What was the problem and how did you attack it? Improved stent needed to treat aneurysms and fistulas associated with blockage of arteries.

- (b) First oral disclosure: Discussed in general terms with Ken Preston 8/14/2003  
Date \_\_\_\_\_ To whom Detailed discussions with Kataphorian and Smith.

- (c) First drawings:

Date 8/15/2003 Dwg. numbers attached

\* attach two copies of the drawings to this form

- (d) First written description:

Date 8/15/2003 by Remker & Kataphorian.  
Shown to or read by whom \_\_\_\_\_

\* attach two copies of the written description to this form

13. Development of invention.

- (a) Date work on development begun: 8/14/2003 — Kataphorian used  
(b) Date completed: sugar nanofibers to make a rebase  
(c) By whom made? layer for a PCL (polycaprolactone)  
(d) Experimental model ☐ Prototype ☒ nanofiber tube that had a diameter  
larger than the diameter of the mandril.

14. First successful test or operation.

- (a) Date of first successful test or operation: The sugar was dissolved and the  
(b) By whom was the test conducted? PCL tube which contained larger loops  
(c) Where are the records of the test? was removed  
(d) Who witnessed the records of the test? Kataphorian.

15. First disclosure OUTSIDE the University.

- (a) Was the discovery disclosed to anyone outside the University or published in any manner?

Yes ☐

No ☒

- (b) Dates: \_\_\_\_\_

- (c) To whom made? \_\_\_\_\_

(d) Where was the disclosure made? (provide details)

\_\_\_\_\_

\_\_\_\_\_

16. First commercial use or sale.

(a) Was the invention used, given, or advertised for sale or sold to anyone outside the University?

Yes ☐

No ☒

(b) Dates \_\_\_\_\_

(c) Provide details of the use, sale, or offer for sale \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

17. Description of discovery.

It is essential to include:

*see attached pages 1-5.*

(a) background information on the purpose of the discovery (i.e., the problem to be solved); and

(b) a detailed description of the discovery or invention (i.e., the solution to the problem) with drawings where possible; and

(c) a discussion of the advantages of the discovery or invention over what was done before.

Be certain to describe the best way of practicing the discovery or invention, and the alternatives to the best way without losing the advantages of the discovery or invention.

18. Most closely related prior publications, prior patents, and prior products or uses.

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

19. Signature(s) of contributor(s).

(1) *Marshall H. Renuker*

Date *8/18/03*

(2) *Morgan Kelly*

Date *8/18/03*

(3) *D. J. ...*

Date *8/15/03*

(4) \_\_\_\_\_

Date \_\_\_\_\_

(5) \_\_\_\_\_

Date \_\_\_\_\_

(6) \_\_\_\_\_

Date \_\_\_\_\_

The foregoing Invention Disclosure consisting of ☐ pages (attached) plus attachments was read and understood by me on the date opposite my name.

Witness(es): include Dean and/or Chair.

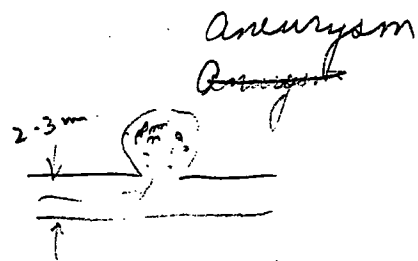
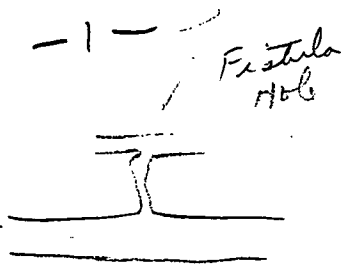
(1) \_\_\_\_\_

Date \_\_\_\_\_

(2) \_\_\_\_\_

Date \_\_\_\_\_

W. R. Renshaw  
8-15-03  
page 1 of 5




Base  
stent can't  
expand enough  
to fill aneurysm  
- close hole.

but - coating the bare stent with  
nanofibers, as we have discussed,  
would prevent <sup>blood cells</sup> from flowing through the  
walls of the stent.

a ~~metal~~ <sup>metal</sup> stent with a nanofiber coating would  
be helpful for all the conditions listed above.

The best contemporary treatment for aneurysm is  
to fill them with tiny metal springs, which cause blood  
to clot and fill the aneurysm with a mechanically strong  
thrombus.

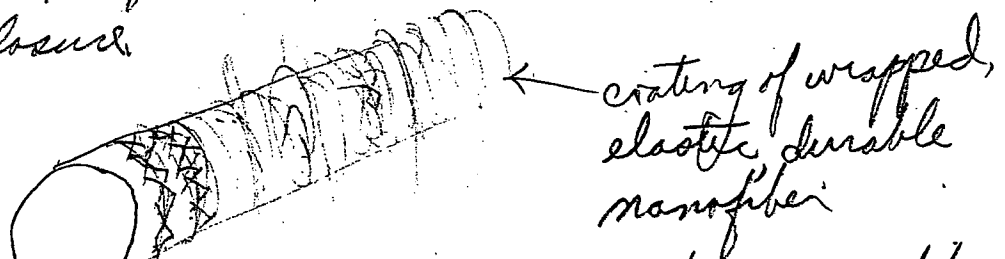
Injection of a fluid mixture of nanofibers into an  
aneurysm would provide  nanofibers  
to capture blood cells and platelets, and form  
a mechanically reinforced thrombus. The chemical  
~~the~~ content of the nanofiber, and the concentration of  
nanofibers can be chosen to optimize the formation of  
a desirable thrombus.

① Device

② method for making the device

③ Chemical composition of the device and substances released from the device

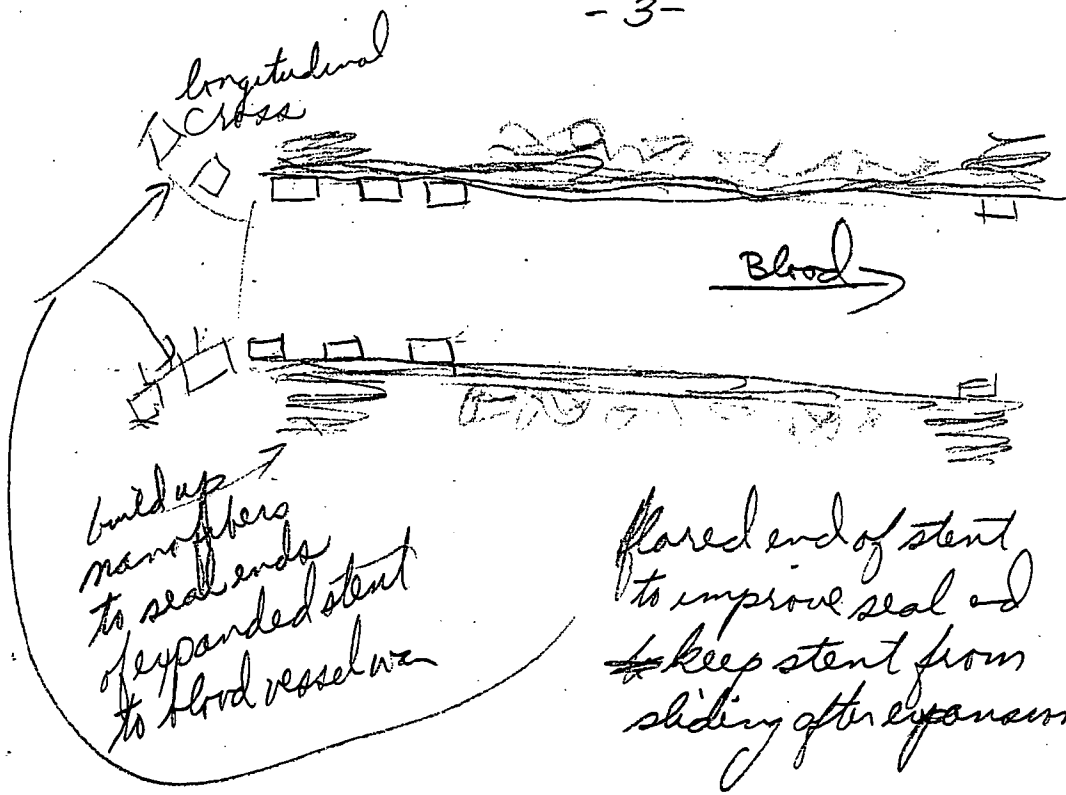
① Device — basically an expandable stent, (metal or polymer), expanded by a balloon (or hydrostatic or osmotic pressure or chemical attachment or reactions between different nanofiber). The stent is coated by a layer of nanofibers that cover the holes, and stretch over the holes when the stent is expanded, as demonstrated in the previous disclosure.



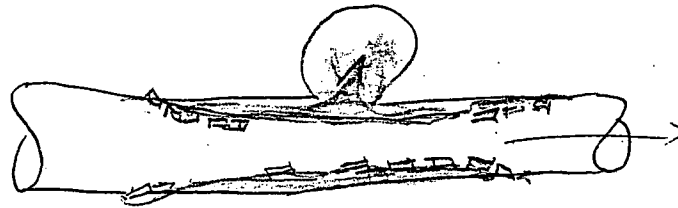
← loose loops of the nanofiber that will ultimately be injected into the aneurysm.

The fact that the fibers are looped around the stent prevents them from moving away from the stent. When wet with blood fluids or other suitable matrix liquids, ~~the~~ the loosely wrapped fibers can flow for a limited distance, long enough to fill the aneurysm.

During insertion the loose loops and matrix liquid, (if used) will be held on the surface of the elastic nanofibers that coat the stent.

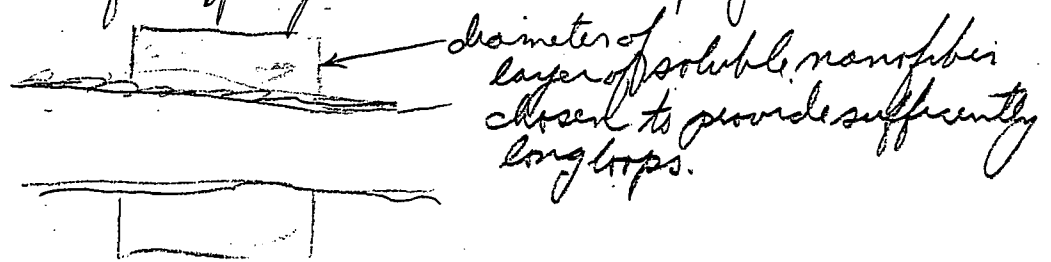


during and after expansion the looped fiber fluid with experience hydrostatic pressure from the blood vessel, ~~the~~ and flow into the aneurysm

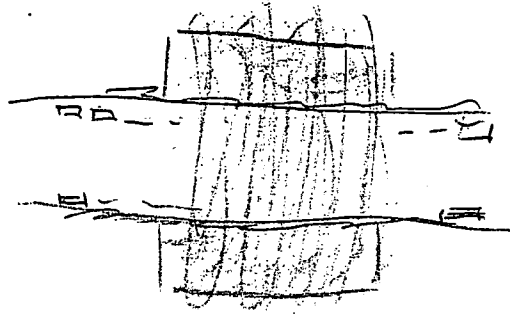


## ② method of making device

- ① wind durable elastic nanofiber onto stent. (electrospinning or other nanofiber making means.)
- ② make a thick layer of soluble nanofiber of sugar or other soluble polymer



- ③ add layer of the nanofiber used to fill the aneurysm

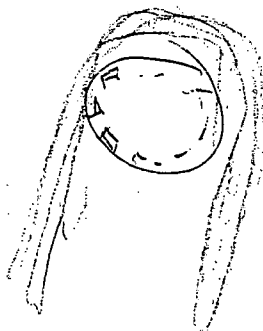


- ④ Dissolve soluble polymer so loops of filling nanofiber collapse onto the durable elastic layer of nanofiber. Supply matrix liquid to filling nanofibers, or rely on blood fluids ~~as~~ as a suitable matrix liquid.

- ⑤ insert assembled device into a catheter for insertion ~~device~~

step 2<sup>nd</sup> <sup>3</sup> might be modified by ~~to~~ spinning a gradient construction of soluble fiber & aneurysm filling fiber at the same time -

or also modified by hanging loops created by slow ~~rotation~~ rotation during spinning of the filling nanofiber & direction of arrival of nanofiber



Alt Remaker  
8-15-03  
page 5 of 5

3 Chemical composition -----

Dan, Tony  
a